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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/533,839	03/14/2006	William G. Kaelin JR.	20363-013 NATL	8237

7590 06/28/2007

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EXAMINER	
HILL, KEVIN KAI	
ART UNIT	**PAPER NUMBER**
1633	

MAIL DATE	DELIVERY MODE
06/28/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/533,839	KAELIN, WILLIAM G.	
	Examiner	Art Unit	
	Kevin K. Hill, Ph.D.	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-34 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-34 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-15, drawn to a transgenic mammal comprising a recombinant nucleic acid molecule stably integrated into the genome of said mammal, said recombinant nucleic acid molecule comprising an E2F responsive promoter operably linked to a nucleic acid encoding a bioluminescent protein, and a method for the production of said transgenic mammal.

Group II, claim(s) 16-18 and 32-34, drawn to a method of identifying a compound capable of modifying an activity of E2F, comprising contacting a transgenic mammal, or a cell isolated therefrom, comprising a recombinant nucleic acid molecule stably integrated into the genome of said mammal.

Group III, claim(s) 19, drawn to a method for detecting a proliferating cell, the method comprising administering luciferin to a transgenic mouse comprising a recombinant nucleic acid molecule stably integrated into the genome of said mouse.

Group IV, claim(s) 20-28, drawn to a method for detecting a proliferating cell, the method comprising administering a nucleic acid comprising an E2F responsive promoter operably linked to a nucleic acid encoding a bioluminescent protein into said cell.

Group V, claim(s) 29-30, drawn to a non-invasive method for localizing a malignant or cancerous cell in a subject, the method comprising introducing to the subject a recombinant nucleic acid molecule comprising an E2F responsive promoter operably linked to a nucleic acid encoding a bioluminescent protein.

Group VI, claim(s) 31, drawn to a method of determining the efficacy of an anti-tumor compound in a subject, the method comprising administering to the subject a recombinant nucleic acid molecule comprising an E2F responsive promoter operably linked to a nucleic acid encoding a bioluminescent protein.

2. The inventions listed as Groups I-VI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical feature for the following reasons:

37 CFR 1.475(c) states:
"If an application contains claims to more or less than one of the combinations of categories of invention set forth in paragraph (b) of this section, unity of invention might not be present."

The common technical feature in all groups is a recombinant nucleic acid molecule comprising an E2F responsive promoter operably linked to a nucleic acid encoding a bioluminescent protein. This recombinant nucleic acid molecule comprising an E2F responsive promoter operably linked to a nucleic acid encoding a bioluminescent protein cannot be a special technical feature under PCT Rule 13.2 because it is shown in the prior art. Schaley et al (J. Virology 74(5): 2084-2093, 2000) teaches a recombinant nucleic acid molecule comprising an E2F responsive promoter obtained from adenovirus type 5 operably linked to a nucleic acid encoding a bioluminescent protein, specifically green fluorescent protein, substantially as claimed in Claims 1, 13, 20 and 29-32.

Each of the Groups II-VI methods are drawn to distinctly different purposes, a performed with distinctly different method steps, and achieve distinctly different results. For example, The special technical feature of Group II is a transgenic cell or organism; whereas, the cells or organisms of Groups III-VI are not transgenic. The special technical feature of Group III is the administration of luciferin; whereas, Groups IV-V comprise the administration of a nucleic acid, and Group VI comprises the administration of a drug.

3. **Claims 1, 13 and 16 are generic to the following disclosed patentably distinct species:** a transgenic mammal comprising a recombinant nucleic acid molecule comprising an E2F responsive promoter operably linked to a nucleic acid encoding a bioluminescent protein stably integrated into the genome of said mammal, wherein Applicant contemplates a multitude of sub-genera of non-human mammals (e.g., pg 1, line 30; pg 17, lines 14-15). The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features. The species are independent or distinct because as disclosed the different species have mutually exclusive characteristics for each identified species. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 and 372 to elect a single disclosed a transgenic mammal species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Claims 29-31 are generic to the following disclosed patentably distinct species: E2F-responsive promoters, wherein Applicant contemplates a multitude of E2F-responsive promoters (e.g., pg 2, lines 11-14). The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features. The species are independent or distinct because as disclosed the different species have mutually exclusive characteristics for each identified species. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 and 372 to elect a single disclosed bioluminescent protein species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Claims 29-31 are generic to the following disclosed patentably distinct species: bioluminescent proteins, wherein Applicant contemplates a multitude of bioluminescent proteins (e.g., pg 2, lines 15-17). The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or

corresponding special technical features. The species are independent or distinct because as disclosed the different species have mutually exclusive characteristics for each identified species. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 and 372 to elect a single disclosed bioluminescent protein species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Claims 29-31 are generic to the following disclosed patentably distinct species: malignant, tumorous or cancer cell types, wherein Applicant contemplates a multitude of cancers (e.g., pg 3, lines 13-15). The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features. The species are independent or distinct because as disclosed the different species have mutually exclusive characteristics for each identified species. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 and 372 to elect a single disclosed malignant, tumorous or cancer cell type species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

This application contains claims directed to the following patentably distinct species:

i) binding polypeptides, as recited in Claims 2 and 25,

ii) E2F-responsive promoters, as recited in Claims 3-5 and 26-27 (Claims 1, 13, 20 are generic),

iii) bioluminescent proteins, as recited in Claims 6 and 28 (Claims 1, 13, 20 are generic),

iv) host cells from which to make a transgenic mammal, as recited in Claim 13,

v) alternative transgenic test subjects, as recited in Claim 16(a),

vi) alternative responses to a compound, as recited in Claims 17-18 and 33-34 (Claims 16 and 32 are generic), and

vii) cancer cell types, as recited in Claim 22.

The species are independent or distinct because claims to the different species recite the mutually exclusive characteristics of such species. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 and 372 to elect a single disclosed species from each of (i-vii) in accordance with the elected invention for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected species,** including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, Applicant must indicate which of these claims are readable on the elected species.

Should Applicant traverse on the ground that the species are not patentably distinct, Applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the

Examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, Applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin K. Hill, Ph.D. whose telephone number is 571-272-8036. The examiner can normally be reached on Monday through Friday, between 9:00am-6:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph T. Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Kevin K. Hill

Q. JANICE LI, M.D.
PRIMARY EXAMINER